

Veterans Walk for Health Subject Checklist



ENROLLMENT ID: 2 ____ ____ 1 .

RANDOMIZATION ID: 2 ____ ____ 2 .

VISIT 3 - Visit 6

Visit 3 Date: ____ / ____ / ____ .

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
3.1	Document height/ weight and BMI. (SC) <ul style="list-style-type: none"> Record in CPRS Cover Sheet (before RD opens VDF in CPRS). scale used (must be same scale used at visit 1). 	
3.2	If participant is diagnosed with HTN (SC) <ul style="list-style-type: none"> If SBP>160 and/or DBP>95 the participant must be put on hold until his physician gives <i>medical clearance</i> to continue. (If participant put on hold, have them sign a new <i>Medical Clearance Form</i>. Give participant phone card and complete <i>Payment Record/Receipt</i>. Contact the participant's physician for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i>, then place it in the Participant's Study File. Reschedule Visit 3 once medical clearance has been received. If medical clearance is not received, complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, have RD complete CPRS Template "T-Research Study: Termination of Study Participation.") 	
3.5	Give participant phone card (SC) <ul style="list-style-type: none"> Complete <i>Payment Record/Receipt</i> and have the participant sign. 	
3.6	Schedule Visit 4 (SC) <ul style="list-style-type: none"> This appointment needs to be five to seven weeks after visit 1 . Give patient an appointment card or write in on <i>Calendar</i>. Note appointment in your planner. 	
3.8	Make 2 copies of <i>Calendar</i> pages completed since Visit 2 if participant is in group 1 or 2 (SC) <ul style="list-style-type: none"> Original stays with participant. copy to RD with participant name and last four digits of the SSN. copy to Participant's Study File. 	
	SOC from Baseline Survey (SC) <ul style="list-style-type: none"> Make sure RD has a copy of pages 4-7 of the <i>Baseline Survey</i> labeled with participant name and last four digits of the SSN, if not provide a copy. 	

Transition from SC to RD

3.7. (3.13, 3.15)	Query for Exercise Related Symptoms and Adverse Events (RD) <ul style="list-style-type: none"> Ask participant if they have had any of the following new symptoms or worsening of existing symptoms since Visit 2: Shortness of breath, Chest pain, Headache, Faintness, Dizziness, Any other problems. (If yes, complete an <i>Adverse Event Form</i> and fax to Ann Arbor. Follow all instructions on <i>Adverse Event Form /Fax Cover Sheet</i>. -this may be delegated to SC. If participant is put on hold, have them sign a new <i>Medical Clearance Form</i>. Have SC contact participant's physician to ask them for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i>, then put it in the study file. Have SC reschedule Visit 3 medical clearance received. If medical clearance is not received, have SC complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, complete CPRS Template "T-Research Study: Termination of Study Participation.") 	
3.11.	Review Activity Log (RD) <ul style="list-style-type: none"> Group 1 Review <i>Calendar</i>, determine average minutes walked per day. Group 2 Review <i>Calendar</i>, determine average step count per day. Groups 3 Upload Sportbrain, determine average step count per day. 	

Veterans Walk for Health Subject Checklist

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
3.12.	Set new walking goals (RD) <ul style="list-style-type: none"> Record on <i>Visit Documentation Form</i> Consider 10-25% increase in step count or time increase of 5 or 10 minutes with participant. 	
3.14.	Update SOC from Baseline Survey. (RD) <ul style="list-style-type: none"> Ask participant to update the copy of pages 4-7 of the <i>Baseline Survey</i> by marking only the answers that have changed since Visit 1. 	
3.16	Nutritional Counseling (RD) <ul style="list-style-type: none"> Use updates SOC (give to SC to provide for you at next visit). Use motivational interviewing techniques. 	
3.16.	Set new nutritional goals. (RD) <ul style="list-style-type: none"> Document on <i>Visit Documentation Form</i>. 	
3.16	Distribute nutritional/walking handouts as appropriate. (RD)	
3.18	<i>Visit Documentation Form</i> to Ann Arbor (SC) <ul style="list-style-type: none"> If CPRS note, print, obliterate name and SSN, write enrollment ID on the top margin. Send to Ann Arbor. 	
4.0	Reminder call to participant before next study visit (SC) <ul style="list-style-type: none"> Date of reminder call: ____/____/____ Remind participant to bring calendar (if in group 1 or 2). Remind participant to wear pedometer to visit (if in group 2 or 3). 	

VISIT 4 (Reinforcement)

Date: ____/____/____.

4.1	Document height/ weight and BMI. (SC) <ul style="list-style-type: none"> Record in CPRS Cover Sheet scale used (must be same scale used at visit 1). 	
4.2	If participant is diagnosed with HTN (SC) <ul style="list-style-type: none"> If SBP>160 and/or DBP>95 the participant must be put on hold until his physician gives <i>medical clearance</i> to continue. (If participant put on hold, have them sign a new <i>Medical Clearance Form</i>. Give participant phone card and complete <i>Payment Record/Receipt</i>. Contact the participant's physician for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i> and place it in the Participant's Study File. Reschedule Visit 4 once medical clearance has been received. If medical clearance is not received, complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, have RD complete CPRS Template "T-Research Study: Termination of Study Participation.") 	
4.5	Give participant subject with phone card (SC) <ul style="list-style-type: none"> Complete <i>Payment Record/Receipt</i> and have the participant sign. 	
4.6	Schedule Visit 5 (SC) <ul style="list-style-type: none"> This appointment needs to be 11 to 13 weeks after visit 1. Give patient an appointment card or write in on <i>Calendar</i>. Note appointment in your planner, note to send Actical 10 days prior to appointment in planner. 	

Veterans Walk for Health Subject Checklist

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
4.7	Explain to participant that he is to wear an Actical for a full 7 days prior to next study visit (SC) <ul style="list-style-type: none"> Will be sent to him 9 days prior to next visit. Confirm that he still has <i>Actical Use Handout</i>, if not dispense a new one. Record dates that the device will be worn on the <i>Actical Wearing Log</i>. Dispense the log to the participant and remind him how to complete it. Add the participant's correct address is on <i>Crosswalk 2</i>. 	
4.11	Make 2 copies of <i>Calendar</i> pages completed since Visit 3 if participant is in group 1 or 2 (SC) <ul style="list-style-type: none"> Original stays with participant. Copy to RD with participant name and last four digits of the SSN. Copy to Participant's Study File. 	
	SOC from Baseline Survey (SC) <ul style="list-style-type: none"> Give RD the updated copy of pages 4-7 of the <i>Baseline Survey</i> for today's visit. 	
Transition from SC to RD		
4.8. (4.14, 4.16)	Query for Exercise Related Symptoms and Adverse Events (RD) <ul style="list-style-type: none"> Ask participant if they have had any of the following new symptoms or worsening of existing symptoms since Visit 3: Shortness of breath, Chest pain, Headache, Faintness, Dizziness, Any other problems. (If yes, complete an <i>Adverse Event Form</i> and fax to Ann Arbor. Follow instructions on <i>Adverse Event Form /Fax Cover Sheet</i> (this may be delegated to SC). If participant is put on hold, have them sign a new <i>Medical Clearance Form</i>. Have SC contact participant's physician to ask for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i> and put it in the study file. Have SC reschedule Visit 4 once medical clearance received. If medical clearance is not received, have SC complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, complete CPRS Template "T-Research Study: Termination of Study Participation.") 	
4.12	Review Activity Log (RD) <p>Group 1</p> <ul style="list-style-type: none"> Review Calendar, determine average minutes walked per day <p>Group 2</p> <ul style="list-style-type: none"> Review Calendar, determine average step count per day <p>Groups 3</p> <ul style="list-style-type: none"> Upload Sportbrain, determine average step count per day 	
4.13	Set new walking goals (RD) <ul style="list-style-type: none"> Record on Visit Documentation Form Consider 10-25% increase in step count or time increase of 5 or 10 minutes with participant. 	
4.15	Update SOC from Baseline Survey. (RD) <ul style="list-style-type: none"> Ask participant to update the copy of pages 4-7 of the Baseline Survey again by marking only the answers that have changed since Visit 3. 	
4.17	Nutritional Counseling (RD) <ul style="list-style-type: none"> Use updates SOC (give to SC to provide to you at next visit). Use motivational interviewing techniques. 	
4.17	Set new nutritional goals. (RD) <ul style="list-style-type: none"> Document on Visit Documentation Form. 	

Veterans Walk for Health Subject Checklist

4.17	Distribute nutritional/walking handouts as appropriate (RD)	
4.19	Visit Documentation Form to Ann Arbor (SC) <ul style="list-style-type: none"> If CPRS note, print, obliterate name and SSN, add enrollment ID to the top margin. Send to Ann Arbor. 	
4.20	Send Actical to participant by overnight mail 10 days prior to Visit 5 (SC) <ul style="list-style-type: none"> Log randomization ID and date dispensed on Actical Log. Set up Actical on Actireader and write user identity (Enrol. ID and V#), start date and time, and participants ht/wt. Make sure the battery life extends beyond the date the participant is to wear the Actical. File overnight mail airbill with Actical Log. 	
4.21	Call Participant to confirm Actical was received (SC) Date of call: ____/____/____ <ul style="list-style-type: none"> Reminder to start wearing Actical the morning of ____/____/____ to get 7 full days of data, and to bring Actical and <i>Actical Wearing Log</i> to appointment. Remind participant to bring calendar (if in group 1 or 2). Remind participant to wear pedometer to visit (if in group 2 or 3). 	

VISIT 5 (Reinforcement)

Date: ____ / ____ / ____.

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
5.1	Document height/ weight and BMI. (SC) <ul style="list-style-type: none"> Record in CPRS Cover Sheet (before RD opens VDF in CPRS) scale used (must be same scale used at visit 1). 	
5.2	If participant is diagnosed with HTN (SC) <ul style="list-style-type: none"> If SBP>160 and/or DBP>95 the participant must be put on hold until his physician gives <i>medical clearance</i> to continue. (If participant put on hold, have them sign a new <i>Medical Clearance Form</i>. Give participant phone card and complete <i>Payment Record/Receipt</i>. Contact participant's physician for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i> and place it in the Participant's Study File. Reschedule Visit 5 once medical clearance has been received. If medical clearance is not received, complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, have RD complete CPRS Template "T-Research Study: Termination of Study Participation.") 	
5.4	Obtain Actical and Actical Wearing Log from participant (SC) <ul style="list-style-type: none"> Upload Actical data to computer to make sure that it recorded properly (at least a full 7 days of data) Save file to be sent with monthly shipment to Ann Arbor. Maintain a copy of the Actical Wearing Log and send original to Ann Arbor. Record that Actical was returned on the <i>Actical Log</i> (If Actical did not record at least 7 full days of data, re-dispense Actical and record on <i>Actical Log</i>. Give participant an <i>Actical Wearing Log</i>, phone card and complete a <i>Payment Record</i>. Reschedule Visit 5 at least 7 full days from today, up to 14 days from today. Give participant an appointment card and document it in your planner.) 	
5.6	Give participant phone card (SC) <ul style="list-style-type: none"> Complete <i>Payment Record/Receipt</i> and have the participant sign. 	
5.7	Schedule Visit 6 (SC) <ul style="list-style-type: none"> This appointment needs to be 23 to 25 weeks after visit 1. Give patient an appointment card or write in on <i>Calendar</i>. Note appt. in your planner, note to send Actical 10 days prior to appt. in planner. 	

Veterans Walk for Health Subject Checklist

5.8	Explain to participant that he is to wear an Actical for a full 7 days prior to next study visit (SC) <ul style="list-style-type: none"> Will be sent to him 9 days prior to next visit. Confirm that he still has <i>Actical Use Handout</i>, if not dispense a new one. Record dates that the device will be worn on the <i>Actical Wearing Log</i>. Dispense the log to the participant and remind him how to complete it. Confirm the participant's is at same address as on <i>Crosswalk 2</i>. 	
5.12	Make 2 copies of <i>Calendar</i> pages completed since Visit 4 if participant is in group 1 or 2 (SC) <ul style="list-style-type: none"> Original stays with participant. copy to RD with participant name and last four digits of the SSN. copy to Participant's Study File. 	
	SOC from Baseline Survey (SC) <ul style="list-style-type: none"> Give RD updated copy of pages 4-7 of the <i>Baseline</i> for today's visit. 	
Transition from SC to RD		
5.9 (5.14, 5.16)	Query for Exercise Related Symptoms and Adverse Events (RD) <ul style="list-style-type: none"> Ask participant if they have had any of the following new symptoms or worsening of existing symptoms since Visit 4: Shortness of breath, Chest pain, Headache, Faintness, Dizziness, Any other problems. (If yes, complete an <i>Adverse Event Form</i> and fax to Ann Arbor. Follow instructions on <i>Adverse Event Form /Fax Cover Sheet</i> (may be delegated to SC). If participant is put on hold, have them sign a new <i>Medical Clearance Form</i>. Have SC contact participant's physician to ask them for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i>, then put it in the study file. Have SC reschedule Visit 5 once medical clearance received. If medical clearance is not received, have SC complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, complete CPRS Template "T-Research Study: Termination of Study Participation.") 	
5.13	Review Activity Log (RD) <p>Group 1</p> <ul style="list-style-type: none"> Review <i>Calendar</i>, determine average minutes walked per day <p>Group 2</p> <ul style="list-style-type: none"> Review <i>Calendar</i>, determine average step count per day <p>Groups 3</p> <ul style="list-style-type: none"> Upload Sportbrain, determine average step count per day 	
5.15	Set new walking goals (RD) <ul style="list-style-type: none"> Record on <i>Visit Documentation Form</i> Consider 10-25% increase in step count or time increase of 5 or 10 minutes with participant. 	
5.17	Update SOC from Baseline Survey. (RD) <ul style="list-style-type: none"> Ask participant to update the copy of pages 4-7 of the <i>Baseline Survey</i> again by marking only the answers that have changed since Visit 4. 	
5.18	Nutritional Counseling (RD) <ul style="list-style-type: none"> Use updates SOC (give to SC to provide to you at next visit). Use motivational interviewing techniques. 	
5.18	Set new nutritional goals. (RD) <ul style="list-style-type: none"> Document on <i>Visit Documentation Form</i>. 	
5.18	Distribute nutritional/walking handouts as appropriate (RD)	
5.20	<i>Visit Documentation Form</i> to Ann Arbor (SC) <ul style="list-style-type: none"> If CPRS note, print, obliterate name and SSN, write enrollment ID on the top margin. Send to Ann Arbor. 	

Veterans Walk for Health Subject Checklist

5.20	Actical Wearing Log and Actical File download to Ann Arbor (SC) <ul style="list-style-type: none"> Maintain copy of <i>Actical Wearing Log</i> in pts study file, send original to Ann Arbor. Save copy of Actical file to hard drive or disc, send to Ann Arbor by email or disc. 	
5.21	Send Actical to participant by overnight mail 10 days prior to Visit 6 (SC) <ul style="list-style-type: none"> Log randomization ID and date dispensed on <i>Actical Log</i>. Set up Actical on Actireader and write user identity (Enrol. ID and V#), start date and time, and participants ht/wt. Make sure the battery life extends beyond the date the participant is to wear the Actical. File overnight mail airbill with <i>Actical Log</i>. 	
5.22	Call Participant to confirm Actical was received (SC) Date of call: ____/____/____ <ul style="list-style-type: none"> Reminder to start wearing Actical the morning of ____/____/____ to get 7 full days of data, and to bring Actical and <i>Actical Wearing Log</i> to appointment. Remind participant to bring calendar (if in group 1 or 2). Remind participant to wear pedometer to visit (if in group 2 or 3). 	

VISIT 6 (Reinforcement)

Date: ____ / ____ / ____.

Flow Chart Reference	BRIEF DESCRIPTION	Check as complete
6.1	Document height/ weight and BMI. (RD TECH) <ul style="list-style-type: none"> Record in CPRS Cover Sheet (before RD opens VDF in CPRS). scale used (must be same scale used at visit 1). 	
6.2	If participant is diagnosed with HTN (SC) <ul style="list-style-type: none"> If SBP>160 and/or DBP>95 the participant must be put on hold until his physician gives <i>medical clearance</i> to continue. (If participant put on hold, have them sign a new <i>Medical Clearance Form</i>. Administer <i>Final Survey</i>, collect all devices and calendar pages. Give participant phone card, t-shirt, and complete <i>Payment Record/Receipt</i>. Contact the participant's physician for medical clearance - if granted have physician sign <i>Medical Clearance Form</i> and place in the Participant's Study File. Reschedule nutritional counseling once medical clearance has been received. If medical clearance not received, complete <i>Participant Dropout/Termination Form</i> and fax to Ann Arbor, have RD complete CPRS Template "T-Research Study: Term. of Study Participation.") 	
6.4	Administer <i>Final Survey</i> (SC) <ul style="list-style-type: none"> Add Randomization ID to top of <i>Final Survey</i>. Remind participant it will take ~20-30 min. to complete, he does not have to complete anything that he doesn't feel comfortable with, and he can ask you if he has questions. Ask if the participant would like to complete the survey independently or if he would like you to read it to him. Review any skipped answers with participant to make sure they were skipped intentionally and not as an oversight. 	
6.5	Obtain Actical and <i>Actical Wearing Log</i> from participant (SC) <ul style="list-style-type: none"> Upload Actical data to computer to make sure that it recorded properly (at least a full 7 days of data). Save file, send file and <i>Actical Wearing Log</i> to Ann Arbor. Record that Actical was returned on the <i>Actical Log</i> (If Actical did not record at least 7 full days of data, re-dispense an Actical and <i>Actical Wearing Log</i> and record on the <i>Actical Log</i>. Give pt phone card and complete a <i>Payment Record</i>. Reschedule Visit 6 at least 7 full days from today, up to 14 days from today. Give the pt an appointment card and document appt your planner.) 	

Veterans Walk for Health Subject Checklist

6.5, 6.11	Obtain Digiwalker / safety strap or Sportbrain / cable / safety strap from participant if in group 2 or 3 (SC) <ul style="list-style-type: none"> Record as returned on the <i>Digiwalker Log</i> or <i>Sportbrain Log</i>. If in group 3, upload Sportbrain so that data is available to the RD at today's visit. 	
6.6	Give participant phone card and T-Shirt (SC) <ul style="list-style-type: none"> Complete <i>Final Payment Record/Receipt</i> and have the participant sign 	
6.11	Collect <i>Calendar</i> pages from participant if in group 1 or 2 (SC) <ul style="list-style-type: none"> Make two copies of pages completed since visit 5. Add pt name and last four digits of SSN to top of 1 copy, give to RD for today's visit. File other copy in Participant's Study File. 	
	SOC from Final Survey (SC) <ul style="list-style-type: none"> Copy of pages 4-7 of the Final Survey, give to RD for today's visit 	
Transition from SC to RD		
6.7 (6.12)	Query for Exercise Related Symptoms and Adverse Events (RD) <ul style="list-style-type: none"> Ask participant if they have had any of the following new symptoms or worsening of existing symptoms since Visit 4: Shortness of breath, Chest pain, Headache, Faintness, Dizziness, Any other problems. (If yes, complete an <i>Adverse Event Form</i> and fax to Ann Arbor. Follow all instructions on <i>Adverse Event Form /Fax Cover Sheet</i>. -this may be delegated to SC). If participant is put on hold, have them sign a new <i>Medical Clearance Form</i>. Have SC contact participant's physician to ask them for medical clearance - if granted have physician sign the <i>Medical Clearance Form</i>, then put it in the study file. Have SC reschedule Visit 5 once medical clearance received. If medical clearance is not received, have SC complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, complete CPRS Template "T-Research Study: Termination of Study Participation.") 	
6.13	Review Activity Log (RD) <p>Group 1</p> <ul style="list-style-type: none"> Review <i>Calendar</i>, determine average minutes walked per day. <p>Group 2</p> <ul style="list-style-type: none"> Review <i>Calendar</i>, determine average step count per day. <p>Groups 3</p> <ul style="list-style-type: none"> Review Sportbrain data (uploaded by SC), determine av. step count/day. 	
6.15	Nutritional Counseling (RD) <ul style="list-style-type: none"> Use SOC from <i>Final Survey</i> Use motivational interviewing techniques. 	
6.15	Set new nutritional goals. (RD) <ul style="list-style-type: none"> Document on <i>Visit Documentation Form</i>. 	
6.15	Distribute nutritional/walking handouts as appropriate (RD)	
	Document Termination of Participation (SC) <ul style="list-style-type: none"> Complete CPRS template "T-Research Study: Termination of Study Participation." 	
6.17	<i>Visit Documentation Form</i> to Ann Arbor (SC) <ul style="list-style-type: none"> If CPRS template, print note, obliterate participant name and SSN, write enrollment ID on the top margin. Send to Ann Arbor. 	
6.17	<i>Actical Wearing Log</i> and Actical File download to Ann Arbor (SC) <ul style="list-style-type: none"> Maintain copy of <i>Actical Wearing Log</i> in pt's study file, send original to Ann Arbor Save Actical file download to hard drive or disc, send to Ann Arbor by email or disc 	
6.17	Send original <i>Calendar</i> to Ann Arbor (SC)	